

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

46. (Amended) A pharmaceutical aerosol formulation comprising a hydrofluoroalkane (HFA) propellant; a physiologically effective amount of a medicament for inhalation; and [a surfactant selected from the group consisting of a C<sub>8</sub>-C<sub>16</sub> fatty acid or salt thereof, a bile salt, a phospholipid, and an alkyl saccharide, wherein the phospholipid is selected from the group consisting of lysophosphatidylcholine, lysophosphatidylglycerol, lysophosphatidylethanolamine, lysophosphatidylinositol, lysophosphatidylserine, diacylphosphatidylcholine, diacylphosphatidylglycerol, diacylphosphatidylethanolamine, diacylphosphatidylinositol, and diacylphosphatidylserine] an alkyl saccharide surfactant.

76. (Amended) A method for the treatment of a patient in need of therapy with a medicament, comprising administering to said patient a therapeutically effective amount of a pharmaceutical aerosol formulation comprising a HFA propellant; a physiologically effective amount of the medicament; and [a surfactant selected from the group consisting of a C<sub>8</sub>-C<sub>16</sub> fatty acid or salt thereof, a bile salt, a phospholipid, and an alkyl saccharide, wherein the phospholipid is selected from the group consisting of lysophosphatidylcholine, lysophosphatidylglycerol, lysophosphatidylethanolamine, lysophosphatidylinositol, lysophosphatidylserine, diacylphosphatidylcholine, diacylphosphatidylglycerol, diacylphosphatidylethanolamine, diacylphosphatidylinositol, and diacylphosphatidylserine] an alkyl saccharide surfactant.

Applicant : Kjell Bäckström et al.  
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REMARKS

Claims 46, 54-77, and 80-83 are now pending, claims 47-53, 78, and 79 having been cancelled by the above amendments. Independent claims 46 and 76 have been amended to require that the formulation contain an alkyl saccharide surfactant, which is supported by original claim 1 as filed. No new matter has been added by any of the above amendments.

The pending claims are rejected under 35 U.S.C. § 102(b) as anticipated by Adjei et al. (U.S. Patent No. 5,676,931), or alternatively under 35 U.S.C. § 103(a) as obvious over Adjei optionally in view of Purewal et al. (U.S. Patent No. 5,695,743). Applicants have now amended sole independent claims 46 and 76 to require the inclusion of an alkyl saccharide surfactant in the formulation. Neither of the cited references suggests or describes the inclusion of an alkyl saccharide surfactant in a formulation, and accordingly the pending claims are patentable over them.

Nevertheless, it is apparently the Examiner's contention that any class of surfactants, including alkyl saccharides, are obvious because such surfactants are known to be equivalent in the art of pharmaceutical formulations. Such a view is inconsistent with what the cited references suggest to the skilled artisan. For example, as the Examiner correctly points out, Adjei does indeed describe a wide range of surfactants to be used in NCFC propellant-based formulations, including fatty acid salts, bile salts, and other compounds (col. 3, lines 1-25). Conspicuously absent from Adjei's list is alkyl saccharides. Thus, having read Adjei, the skilled artisan would be aware of a number of possible surfactants for use in formulations, but the skilled artisan would encounter absolutely no suggestion to go outside Adjei's classes of available surfactants and choose an alkyl saccharide surfactant. Clearly not all surfactants are the same or would be deemed to be equivalents by a skilled artisan, given the cited references. It is insufficient for the Examiner to simply say that alkyl saccharides are equivalent to other surfactants without providing evidence that that is the case. Therefore, the examiner has failed to produce a prima facie case of obviousness for the pending claims.

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Applicants ask that all claims be allowed. Enclosed is a Petition for Extension of Time with the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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